



# OpenSpecimen

## Informatics Platform for Biobanks

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# OpenSpecimen - An Open Source Biobanking Informatics Platform

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## Introduction

OpenSpecimen is a high configurable web based [open source](#) biobanking informatics platform. It is used in 60+ biobanks across 15+ countries including leading clinical research centers like Stanford, Johns Hopkins, Univ of New South Wales, Univ of Melbourne, Singapore General Health ([click here to see user directory](#)).

Our primary focus is to enable biobanks collect “high quality data”. We strongly believe specimens without annotations are of no use. Biobanking is a very diverse field. Therefore, one solution will not meet all the needs. Therefore, OpenSpecimen is designed to be a highly configurable and customizable solution.

OpenSpecimen is an open source software. That means, users have access to the source code and are not at the mercy of a single vendor for support and development. Unlike most commercial LIMS, OpenSpecimen can be used for unlimited users and studies. Being open source, there is a strong sense of “community” across OpenSpecimen users. Krishagni conducts annual users’ meet in US and Australia, monthly community calls and online forums for community interactions.

This document provides you with a comprehensive overview of OpenSpecimen and why it is best suited for your biobank.



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## Product Highlights -

This section describes the features of OpenSpecimen as being the most compatible model for the informatics needs of your biobank.

### Feature rich, rapidly improving

OpenSpecimen enables you to collect specimen annotations, track inventory and specimen utilization. It is rapidly improving as new users join the community. We follow Agile development processes with a new version being released every 3-4 months, enabling our users to take advantage of the new features.

Refer to Section “Features” below for complete list.

### Highly configurable

Every biobank or study has different collection needs. Some biobanks collect specimens for longitudinal studies, some collect leftover samples from hospitals, and some both. The workflow, SOPs, and data collection needs of each biobank could be different. Therefore, a “one size fits all” solution will not suit every biobanks.

One of the powerful aspects of OpenSpecimen is its configurability to meet local needs. Screens, lists, reports, custom forms and fields, multiple data entry modes, etc can be designed differently for each study within a single instance of OpenSpecimen.

### Enterprise solution (i.e. multi-biobank support)

A single instance of OpenSpecimen can support multiple biobanks within an institution. It can also support large multi-site studies with 100s of users collecting millions of specimens. This coupled with its configurability enables our users to utilize the system as a central biobanking informatics platform - i.e. as the “Enterprise solution”.

### Open source license

OpenSpecimen is available under [BSD 3 license](https://www.fsf.org/licenses/licenses.html) which allows users to modify the source code and to meet local needs. The important aspects of open source are:

1. No vendor lock-in
2. Sense of community and collaboration
3. Access to source code for audit, modification and customization
4. Lower cost of ownership

A word of caution about “code customization” popularly known as “forking” in open source world. Forking will result in you being left out of all the future improvements in the main edition. Instead of customizing the main code base, we suggest developing “plugins” on top of OpenSpecimen. Plugins are similar to smartphone apps in iOS or Android where it utilizes the APIs of the underlying framework.



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## Community experience

Krishagni has worked very hard to develop a vibrant user community which contributes heavily towards:

- a. Funding new features, integrations, plugins etc.
- b. Annual community meetups
- c. Monthly community calls
- d. Frequent interactions on Q&A forums

## Plugins and marketplace

There are many free plugins available with the Enterprise edition which can be reused as-is or with modifications. Krishagni's website hosts a marketplace for plugins.

[Refer to this link to learn more about plugins and how to develop them.](#)

## Latest technology stack

OpenSpecimen is developed using the latest technology stack including the following:

1. Angular 1.x (in process of upgrading to Ang 2.x)
2. Java 1.8 and Spring
3. Latest versions of JBoss, Tomcat, MySQL, Oracle, etc.
4. 100% REST API based

## Users case studies

- [Johns Hopkins University](#), Baltimore, USA
- [University of Leicester](#), Leicester, England
- [Emory University](#), Atlanta, Georgia
- [Victorian Cancer Biobank](#), Melbourne, Australia



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## Feature Highlights

OpenSpecimen is a “biospecimen centric” application with the following goals:

1. Collect specimen annotations
2. Powerful and easy to use reporting
3. Specimen accession and inventory management
4. Security and traceability (audit)

## User and role management

OpenSpecimen’s access control enables the following:

- a. Customizable access control e.g. PHI data, who can create freezers, protocols, etc.
- b. Multiple biobanks support (multi-tenant)
- c. Multiple studies conducted in one or more biobanks

Users can be assigned different roles at different levels like, “study level” or “site level”. E.g.

1. John is “technician” for “Breast cancer protocol”
2. John is “supervisor” for “Lung cancer protocol”

OpenSpecimen is installed with default roles and new roles can be created as per local needs.

## Reporting, specimen carts and dashboarding

Reporting is one of the most powerful feature of OpenSpecimen. According to our users, this is one of the best features of OpenSpecimen

### Reporting

1. Get data based on one or more filters including a complex combination of operators such as, ‘and’, ‘or’, ‘intersection’, ‘parenthesis’ etc.
2. Hierarchical query support: e.g. query specimens based on the conditions of parent specimen.
3. Calculated filters for dates and integers, e.g. minutes\_between, last\_month, etc.
4. Pivot table based reports (e.g. count of samples per anatomic site further divided by per specimen type)
5. Saving queries for future use, organizing in folders, and sharing with other users.
6. Export and import query definition
7. Export data into CSV files
8. Add specimens to a pick-list to distribute, ship, or to perform any other bulk operation.

See Appendix - Example queries.

### Specimen carts (pick lists)

A “specimen cart” allows users to shortlist specimens of interest for further processing.

A user can:

1. Create multiple carts and save it
2. Share it with other users

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3. Perform bulk operations like ship, distribute, add annotations, delete, transfer, etc.
4. Fetch from automated freezer

## Dashboarding (EE version only)

The administrator can configure Collection Protocol (CP) specific dashboards to provide a graphical overview of the project to the end users. E.g. pie chart of specimens available by type, pathology status, anatomic site, etc.

## Containers (inventory management)

A “container” can be a room, freezer, rack, shelf, box, etc. OpenSpecimen does not dictate a specific hierarchy of containers. You can create the containers and its hierarchy as per local needs.

### Feature highlights:

1. Predefine “container types” to create complete hierarchy in a single-click
2. Restrict samples by type or collection protocol: E.g. “blood” box, “DNA” box for “breast cancer collection protocol”
3. Create containers in bulk
4. Export contents of a container for auditing
5. Transfer boxes from one freezer to another
6. Bulk transfer specimens from one location to another.
7. “Dimensionless” containers i.e. with no predefined dimensions.
8. Multiple auto-allocation algorithms to suggest the best position for the specimen being stored.

## Custom forms and fields

Based on the data of interest, you might want to create extra fields, forms or questionnaires to collect data. E.g. smoking history, family history, pathology annotations, test results, etc.

### Feature highlights:

1. Create new forms and fields via user interface without any IT support.
2. Support for all standard field types like, text, numeric, multi-line, radio-button, dropdown, date, file, etc.
3. Export/import forms from one instance to another.
4. Include custom fields within existing screens or as a separate tab.
5. Custom forms available in reporting and dashboard modules.

Refer to Appendix for custom form examples and documentation.

## Biospecimen collection

A “collection protocol” in OpenSpecimen defines the SOP under which specimens will be collected and processed. E.g. a clinical study/trial, disease based collection.

At a high level, the CP allows to configure the following:

1. Study calendar with event time-points and specimen collection details
2. Format for subject ID and specimen label generation
3. Printing

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## 4. Bulk pre-printing and collection kit creation

### Multi-site longitudinal study

A collection protocol can include the following:

- Specimen collection calendar including, time points (day 0, day 30, etc), the primary specimens expected, and the processing of each specimen. E.g. create plasma and serums from blood, aliquots, etc.
- Label generation and printing configuration, consent statements, monthly reports, catalog, etc
- Custom forms and questionnaires for collecting study specific data

### Disease based or left-over samples collections

Users can define a CP with a single event and the specimens that are expected per participant. In case some of the specimens are not collected or additional specimens are collected, these deviations can be handled during real time.

Based on the disease, additional custom fields can be added and the screens can be customized to include new fields.

### Consent tracking

Tracking consents for specimens can be important, especially if you are going to distribute them for research. Before distribution, you might have to check if the consents of the study subjects match with the project being distributed.

OpenSpecimen supports consent tracking at various levels:

- a. Individual consent tiers
- b. Consent PDF upload
- c. Both

You can define the consent tiers in a collection protocol and collect individual participant's responses. Alternatively, you can upload consent PDF per participant.

The disadvantage of uploading consent PDFs is that it cannot be used for query or reporting since the data is within the files.

### Configurable User Interface

Many of the screens can be configured as per local needs without any programming changes i.e. local administrators can do it without any external help. Depending on the data collection needs of a study, new fields can be added to the participant, visit and specimen pages. In other words, each study can have its own screen design.

Refer to "Appendix - Configurable Screens" for examples of different screen designs.

### Label generation and printing

Specimen labels can be auto-generated and printed from OpenSpecimen. Label can contain a variety of details like CP code, visit code, sample type, collection year, etc. This can be configured at the study level.

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Note about printing: OpenSpecimen is compatible with printing software like Bartender, NiceLabel, etc. These software support any kind of printers and typically cost between \$500-\$1000 USD.

## Distributing specimens to researchers

Specimens can be distributed to researchers to be used in different studies. All distributions are done according to a "Distribution protocol" (DP). A distribution protocol creates a list of specimens need to be distributed, the number of remaining/to be sent samples, and invoices for services. You can also set consents for a distribution protocol. The system will validate if the specimens are consented for this DP.

## Shipping specimens to offsite storage locations

Often, in large repositories, the specimens are stored in offsite long term storage locations. These specimens are then shipped back and forth from the storage locations to the biobanks. The shipping module supports the tracking of specimens from one location to another - sending, receiving, and storage.

## Importing bulk data (CSV)

OpenSpecimen supports importing CSV files for (almost) all objects including, site specific custom fields and forms. This feature is used for legacy data migration and integration with external databases or instruments.

## Audit

Every action of a user from login to logout is audited. The audit information includes the date-time, user id, IP address, old value and the new value. In the next version, audit reports can be generated from the user interface at a collection protocol level. E.g. Viewing all activities on a protocol for a specific user or time frame.

## Security

Following security measures are available in OpenSpecimen:

1. HTTPS for SSL based encryption for data to and from the server.
2. Integrate with institute's LDAP
3. For local accounts (non-LDAP), password complexity, expiry and other password related security measures can be configured in OpenSpecimen.
4. Accounts are locked after certain days of inactivity or incorrect password attempts.



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## Enterprise edition (EE)

The OpenSpecimen EE has additional plugins with time and time bound support from Krishagni.

### Support

Krishagni provides 24x7 support services for users using OpenSpecimen. There are three levels of support packages and are described on the [website here](#).

### Enterprise plugins

The enterprise plugins are available for free for users with the support contract. The plugins currently available are:

- a. Specimen catalog
- b. Tissue microarray (TMA)
- c. Graphical dashboards
- d. Biospecimen requests
- e. Rapid data entry (barcode based)

## Tissue microarray (TMA)

This plugin allows creation of specimen arrays with existing specimens so that it can be tracked, processed and created into slides. Additional annotations can be captured by creating custom forms and fields.

## Dashboards

Dashboards are graphical representation of the current status of the CP. Each CP can have a different dashboard and can be configured by the administrator (i.e. without any programming changes). The graphs can also be embedded in an external website to display live data, e.g. in the website for biobank or study.

## Invoicing

This plugin supports invoicing for services provided during a distribution. It does not yet support per sample storage or processing costs and will be supported in the future.

## Specimen requests

Researchers can search for specimens of interest and submit a request. Once a request is submitted, it notifies the respective staff for further action - usually to distribute or ship specimens.

## Specimen catalog

Specimen catalog is an online web store for your biobank which helps you in better utilizing the specimens in your biobank. It provides the following features:

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- a. Create a filter for the specimens to be displayed in the catalog (i.e. to display only the specimens you wish to make public and without any identifier)
- b. Configure the data fields displayed in the catalog
- c. Configure a request form
- d. Create a visually appealing dashboard page
- e. Allow users to filter specimens of interest and add to cart
- f. Fill the request form and submit.
- g. This will create a request in OpenSpecimen for administrators to review and approve or reject.

## Integration with databases and instruments

### Redcap (RC) and OpenClinica (OC)

OpenSpecimen can be integrated with RC and OC to enable powerful queries across the two systems. For instance., a study is running where biospecimen information is present in OpenSpecimen and clinical data is present in OpenClinica/RedCap.

This plugin will pull the complete dataset per the study including Case Report Form (CRF) data from RC/OC into OpenSpecimen. The RC/OC CRFs are duplicated in OpenSpecimen such that they are now available via the OpenSpecimen reporting module. This will enable users to execute highly powerful queries to search for specimens of interest.

This is available via Krishagni's KrisDB product which enables biobanks to integrate data from multiple sources into an easy to use reporting and dashboarding interface. KrisDB is available under a separate license.

### EPIC (or any EMR)

The goal of integration with EMR is to eliminate duplicate data entry and human errors. Krishagni has integrated EPIC in three different ways for various clients. This approach can be used for any other EMR systems.

1. HL7 feed
2. Direct web service call to EMR
3. Nightly feed from EMR

### Pathology reports

Pathology reports can be loaded in OpenSpecimen either via a HL7 message from Cerner, CoPath, etc or manually uploading the reports via the user interface. These reports can be manually de-identified via the user interface or de-identified in bulk using de-identification algorithms.

### Automated freezer

OpenSpecimen can be integrated with automated freezers like Hamilton, Liconic, TTP Labtech, Brooks, etc using the web-services exposed by these vendors. The automation will include:

- a. Introducing put-list of new barcodes to the freezer during sample storage

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- b. Initiating sample retrieval for a list of samples in the pick list.
- c. Tracking alerts from freezers like temperature changes.

## REST APIs

OpenSpecimen is a 100% REST API enabled application, i.e. every operation visible in the user interface is also available via an API. This is an important aspect of OpenSpecimen because REST APIs

- 1. Are easy to use
- 2. Are language agnostic
- 3. Makes it easy to integrate with external instruments and databases.
- 4. Makes it easy to customize or build new plugins without breaking main code branch of OpenSpecimen

## Customizing to meet local needs

Biobanking is a very diverse field with every biobank's operation different from each other. Therefore it is important for the informatics platform to be easy to customized as per local needs.

A large portion of the end user requirements can be achieved via "configuration" i.e. without requiring any programming support. For the ones which are not achievable via configuration, they can be developed using "plugins".

A "plugin" is like an iPhone or Android app, i.e. it is built on top of OpenSpecimen by using the OpenSpecimen APIs. This approach will ensure that the plugins will continue to work as newer versions of OpenSpecimen are released.. There might be minor tweaks needed with major upgrades similar to iOS/Android upgrades whensome of the apps stop working and need upgrades.

We have developed many plugins with most of them being free and open source., Some of these plugins are available for Enterprise customers at no cost.



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## Online resources

Source code	<a href="https://www.github.com/krishagni/openspecimen">www.github.com/krishagni/openspecimen</a>
Help (Wiki)	<a href="http://help.openspecimen.org">help.openspecimen.org</a>
Issue tracking	<a href="http://track.openspecimen.org">track.openspecimen.org</a>
Videos and YouTube channel	<a href="http://www.openspecimen.org/video">www.openspecimen.org/video</a>
Marketplace	<a href="http://www.openspecimen.org/marketplace/">www.openspecimen.org/marketplace/</a>



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## Appendix

### Custom form example

Forms **Breast Pathology Annotation**

Summary Add/Edit Control Preview

**Breast Pathology Annotation**

- Specimen Procedure (specimenProcedure)
- Tumor Tissue Site (tumorTissueSite)
  - Site (site)
  - Tissue Side (tissueSide)
  - Other Site (otherSite)
- Primary Tumor Stage (primaryTumorStage)
- Distant Metastasis (distantMetastasis)
  - Metastasis Stage (metastasisStage)
  - Tissue Site (tissueSite)
  - Other Tissue Site (otherTissueSite)
- Lymph Node Stage (lymphNodeStage)
- Matted Nodes (mattedNodes)
- Histologic Grade (histologicGrade)
  - Grading System Name (gradingSystemName)
  - Grade (grade)
  - Other Grading System Name (otherGradingSystemName)
  - Tumour Greatest Dimension(cm) (tumourGreatestDimension)
  - Lymphatic Invasion (lymphaticInvasion)
  - Venous Invasion (venousInvasion)
  - Perineural Invasion (perineuralInvasion)
  - Lymph Node Sampling (lymphNodeSampling)
- Breast Margin (breastMargin)
  - Margin Status (marginStatus)
  - Closest Distance To Tumor (closestDistanceToTumor)
  - Extent Of Involvement (extentOfInvolvement)
  - Other Extent Of Involvement (otherExtentOfInvolvement)

**Tumor Tissue Site**

Site	Tissue Side	Other Site
Breast - Central	Left	
Breast Lower Inner Quadrant	Right	

**Primary Tumor Stage**

pTX - Primary tumor cannot be assessed

**Distant Metastasis**

Metastasis Stage	Tissue Site	Other Tissue Site
pMX - Distant Metastasis Cannot be ...		

**Lymph Node Stage**

**Matted Nodes**

Absent  Cannot be determined  Not Applicable  
 Not Specified  Present

**Histologic Grade**

[Click here to read more details here](#)



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## Configurable screens

### Example 1: Breast tumor biobank

<b>Patient ID</b>	<input type="text" value="Patient ID"/>
<b>Last Name</b>	<input type="text" value="Last Name"/>
<b>First Name</b>	<input type="text" value="First Name"/>
<b>Date of birth</b>	<input type="text" value="Date of birth"/>
<b>Procedure</b>	<input type="text" value="Procedure"/> ▼
<b>Histologic Type</b>	<input type="text" value="Histologic Type"/> ▼
<b>Sample ID</b>	<input type="text" value="Sample ID"/>
<b>Type</b>	<input type="text" value="Type"/> ▼
<b>Lineage</b>	<input checked="" type="radio"/> New <input type="radio"/> Derived <input type="radio"/> Aliquot
<b>Created On</b>	<input type="text" value="Created On"/>
<b>Volume</b>	<input type="text" value="Volume"/>
<b>Location</b>	<input type="text" value="Container"/> ▼ <input type="text" value="Row"/> <input type="text" value="Column"/> <input type="text" value="Q"/>

### Example 2: Microbiome biobank (collecting in bulk)

OPENSPECIMEN DEMO

Microbiome Study  
Collect Specimens

Deposit Details

Name: Deposit\_126\_305\_20161005\_1143 Description: \_\_\_\_\_

No File Selected

Download Template

Host ID	Host Age	Host Gender	Filler Order Number	Date of Collection	Isolate Number	Organism name	Specimen Class	Specimen Type	Tube Number	Location





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## Example 3: Animal biobank

The screenshot shows the 'Collect Specimens' form in the OpenSpecimen application. The form is titled 'Diabetes in Cats - SLU' and 'Collect Specimens'. It features a search bar at the top with the text 'Quick Search'. Below the search bar, there is a list of input fields for specimen collection, including: Animal Id, Birth Year, Gender, Vital Status, Breed, Age, Weight, Color, Site, Specimen Type, Initial Quantity, Storage Location (with sub-fields for Container, Row, and Column), and Received Date. At the bottom of the form, there are two buttons: 'Collect' and 'Discard'.

## Examples of queries

### Create a task that will generate additional DNA pairs for genome analysis.

Show all female (Participant.sex) lung (participant.cancer\_type) cancer participants who have lung (tissue site) tumor (tissue type) RNA (sample type) (>5 ug) (sample quantity) AND lung (tissue site) tumor(tissue type) DNA(sample type) (>5 ug) (sample quantity) from a lung (tissue site) tumor(tissue type) specimen with at least 50% neoplastic cellularity (Specimen QA) AND participant-matching DNA (sample type) (>5 ug) (sample quantity) from non-malignant (tissue type = normal) tissue OR normal (tissue type = normal peripheral blood leukocyte) peripheral blood leukocytes(tissue site). Return values of Sample ID number, Sample quality, Sample concentration, Sample amount, and Sample location.

### Create a task that will generate additional DNA pairs for genome analysis

Show all female lung cancer participants who have tumor RNA (> 5 ug) AND tumor DNA (>5 ug) from a tumor specimen with at least 50% neoplastic cellularity AND corresponding non-malignant tissue OR peripheral blood leukocyte specimens that have not yet been converted into DNA. Return values of Specimen ID number, specimen availability, and specimen location.

### Find a unique set of participants for genome analysis

Show all lung cancer patients who have had lung tumor specimens collected AND who have also had a second, non-lung tumor collected. Return values of Specimen ID number, specimen availability, and specimen location.



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## **Find participants for a serum biomarker study**

Show all lung cancer patients for whom a pre-operative serum sample, a 30-120 day post-operative day serum sample, and a primary tumor tissue sample has been collected. Return values of Specimen ID number, specimen availability, and specimen location.

## **Looking for slides to distribute for a tumor tissue survey study**

Find all segments of type "frozen section slide" that are status=available and that correspond to tissue class="primary" tumor. Return values of segment ID number, specimen ID number, tissue site, date created, quantity, and storage location.

## **Preparing a utilization review report**

Return all specimens / segments / samples distributed in the past year. Order by USER, then by distribution date.

## **Looking for potential pairs of primary and relapse tumor specimens**

Return all participants where tumor specimens have been collected at multiple time points.

## **Query for samples based on list of MRNs**

User has a list of MRNs for participants who were given a treatment (or treated with drug 'X'). The user needs to check for samples taken from these participants and stored in the biobank.